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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,505	09/22/2003	Paul C. Weaver	8932-852-999	5819

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EXAMINER	
SWIGER III, JAMES L	
ART UNIT	**PAPER NUMBER**
3733	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,505	WEAVER ET AL.	
	Examiner	Art Unit	
	James L. Swiger	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-59,62-64,67,68,70,73-87,90-92,95,96 and 98-100* is/are rejected.

7)☒ Claim(s) *60-61, 65-66, 88-89, and 93-94* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

In claim 47 there exits an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble, line 1, applicant recites "a bone plating system" with the person's own long bone being only functionally recited, i.e. "for improving the stability of a bone in a long bone...", thus indicating that the claim is directed to the subcombination, "A bone plating system... ". However, in claims 65 and 66, applicant positively recites the person's own tibia and femur as part of the invention, i.e. "a bone plating system of claim 47, wherein the long bone is the tibia/femur", thus indicating that the combination, the bone plating system and the tibia/femur, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Since claiming the combination of the plating system and the person's tibia/femur makes such claim(s) directed to non-statutory subject matter, applicant should amend the claims so as to remove all positive recitations of the person's tibia/femur. As such, the claim(s) would be directed to the subcombination, the bone plating system, and will be considered as such for examination purposes.

In claim 73 there exits an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble, line 1, applicant recites "a bone plating system" with the person's own long bone being only functionally recited, i.e. "for improving the stability of a bone in a long bone...", thus indicating that the claim is directed to the subcombination, "A bone plating system... ". However, in claims 93 and 94, applicant positively recites the person's own tibia and femur as part of the invention, i.e. "a bone plating system of claim 73, wherein the long bone is the tibia/femur", thus indicating that the combination, the bone plating system and the tibia/femur, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Since claiming the combination of the plating system and the person's tibia/femur makes such claim(s) directed to non-statutory subject matter, applicant should amend the claims so as to remove all positive recitations of the person's tibia/femur. As such, the claim(s) would be directed to the subcombination, the bone plating system, and will be considered as such for examination purposes.

Claim Rejections - 35 USC § 103

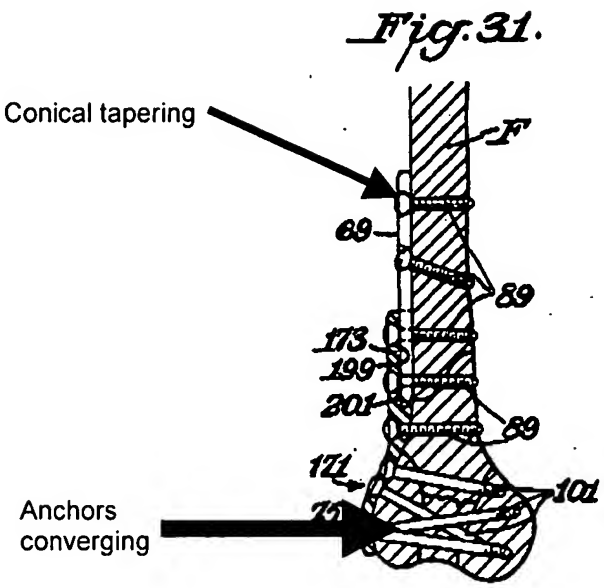
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 47-49, 55-57, 59, 62-64, 67-68, 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. (U.S. Patent No. 5,190,544) in view of Bono (U.S. Patent No. 5,954,722).

Chapman et al. discloses a device having a bone plate (Fig. 29), having an upper (away from the bone, see profile in Fig. 31) and lower surface (towards the bone), a shaft portion (171) having a width, a head portion (175) that flares outward (see profile in Fig. 31) that is greater than the width of the shaft (Fig. 29) and has at least three holes (Fig. 29) that are conically tapered and allow the inserted anchors to converge towards one another (see Fig. 31 below). Because the head flares outward, it may also be considered in a different plane. Since the plate curves outward as it flares, it also has at least two planes, since a curve lies in an infinite number of planes. Chapman et al. also discloses a shaft having a plurality of holes (Fig. 29), a device having a shaft portion with a central axis, and wherein the holes are offset from the central axis (Fig. 29) and alternate sides from the center forming a staggered arrangement. In the device disclosed by Chapman et al., any of the holes are capable of functioning as a provisional fixation hole; likewise that hole is capable of accepting a suture for the provisional fixation.



Chapman et al. discloses the above device except for a bone plating system having holes that are at least partially threaded, a bone plate that has a thinner cross section in regions between the plate holes, a threaded portion of the bone anchor holes that may have a multiple-lead thread, or a plate that curves along a direction transverse to the longitudinal axis of the shaft portion. Bono '722 discloses the items directly *supra*, including threads (123) or multiple-lead threads (124), that enable the bone screws to be frictionally and securely locked into the plate to prevent movement when attached to the bone (Col. 2, lines 42-45), a plate cross section that shows a thinner cross section between the holes and the plate (see Fig. 6 below) and a curved bottom of the plate along the shaft (see Fig. 6 below). These modifications allow for the plate to optimally fit in its applicable uses, such as its use in long bone fracture fixation. The thinner cross section allows the plate to bend more easily to fit into these configurations (Col. 3, lines

50-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Chapman et al. having at least holes that are partially threaded or multiple-lead threaded, or a plate having a thinner cross section between the holes, or a plate that curves transverse to the longitudinal axis in view of Bono so the plate better fits into its use as a femoral fixation system.

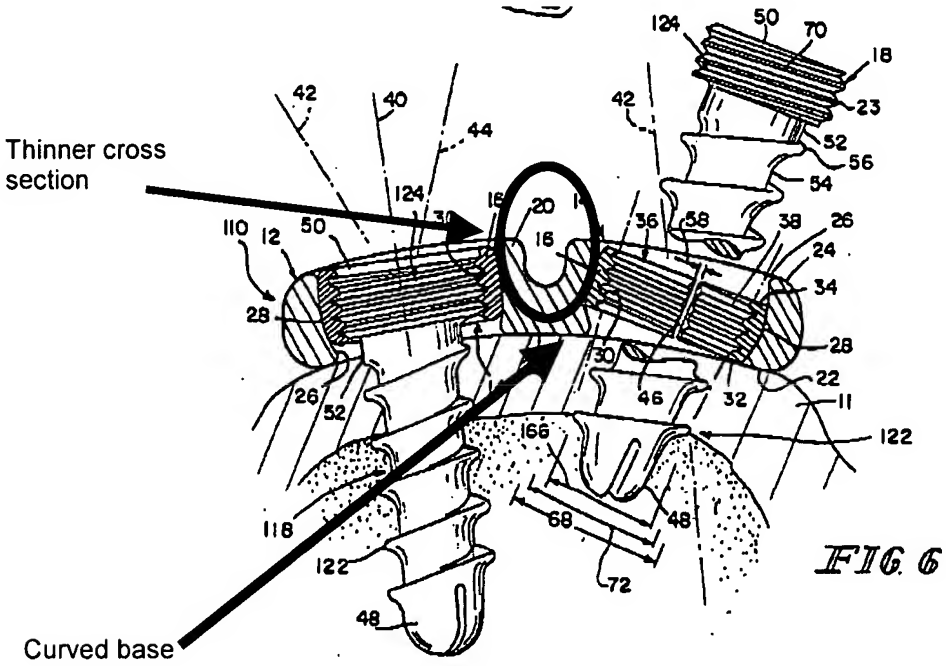


FIG. 6

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. '544 in view of Bono '722 as applied to claim 47 above, and further in view of Kyle et al. (U.S. Patent No. 5,749,872). The combination of Chapman et al. and Bono disclose the above device except for a bone plating system having at least 5 holes in the shaft portion. Kyle et al. discloses a bone plating system having at least 5 holes, allowing the plate to be better secured to the femur (Col. 4, lines 45-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made

to construct the device of Chapman et al. in view of Bono having at least a plate with 5 holes in the shaft portion further in view of Kyle et al. to better secure the plating system to femoral region in its intended use.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. '544 in view of Bono '722 as applied to claim 47 above, and further in view of Trebing. et al. (U.S. Patent No. 5,601,553). The combination of Chapman et al. and Bono disclose the claimed invention except for a plating system wherein at least two of the holes in the head portion are of different diameters. Trebing et al. disclose a device having two holes of different diameters in the head portion (see Fig. 1 below for a diagram of what is considered the head and shaft) that enables the user to better secure the plate in place (Col. 1, lines 55-61). It should be noted that even though Trebing et al. discloses that the larger holes may be used for temporary screws, this reference as modified by Chapman et al. in view of Bono where all screws may be threaded in the head, enables the device of Trebing et al. to better secure the plate onto the femur.

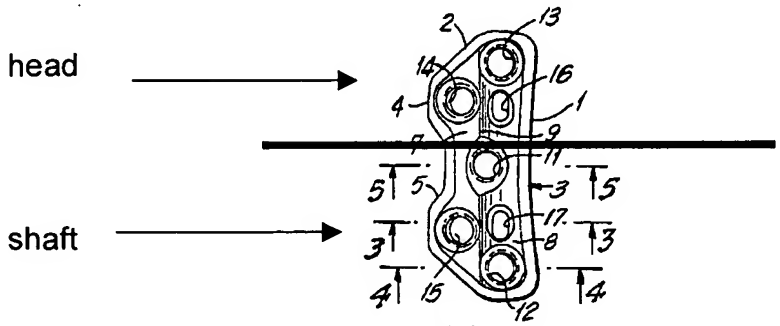


FIG. 1

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Chapman et al. in view of Bono having at

least two holes in the head portion of different diameters in further view of Trebing et al. in order to better secure the plate to femur in use.

Claims 52, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. '544 in view of Bono '722 as applied to claim 47 above, and further in view of Talos et al. (U.S. Patent No. 5,709,686). The combination of Chapman et al. and Bono disclose the claimed invention except for a device having holes in the shaft portion having at least a portion that is smooth, where the smooth portion is at the upper part of the hole, and wherein the smooth upper portion tapers inward in the direction from the upper surface. Talos et al. teaches a bone plate with holes partially smooth (3), and a smooth upper portion that tapers inward (5). These modifications of the bone plate allow for the best-fitting and secure attachment of screws once attached and affiliated with the plate (Col. 1, lines 22-32, and 47-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Chapman et al. in view of Bono having at least holes partially smooth with an inwardly tapering upper portion in further view of Talos et al. to better secure the screws to the plate.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. '544 in view of Bono '722 as applied to claim 59 above, and further in view of Berger et al. (U.S. Patent No. 5,674,222). The combination of Chapman et al. and Bono disclose the claimed invention except for a shaft portion with a trapezoidal-shaped cross section. Berger et al. disclose a trapezoidal cross section capable of also being fitted in between the regions between the plate holes (see Fig. IA) for the

purpose of reducing bone coverage by the shaft and promoting bone growth (Col. 2, lines 32-37).

With regard to claim 69, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone plating system of the combination of Chapman et al. in view of Bono and further in view of Talos et al. having screw holes between the diameter of 5-7mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 71-77, 79, 84-85, 87, 90-92, 95-96, 98-100 rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. '544 in view of Bono '722. Chapman et al. discloses a device having a bone plate (Fig. 29), having an upper (away from the bone, see profile in Fig. 31), and lower surface (towards the bone), a shaft portion (171) capable of fitting along the diaphysis of the bone, a head portion (175) that curves upward (see profile in Fig. 31) and that is greater than the width of the shaft (Fig. 29). The head portion may be defined to have a plurality of conically tapered holes (See Fig. 31 *shown above*). Chapman et al. also disclose a device having holes that are offset from the central portion (Fig. 29), a device where the holes in the head are capable of having a non-perpendicular orientation with respect to the upper surface of the plate (Col. 20, lines 65-68, Col. 21, lines 1-2), and a device where the shaft comprises holes without threads (Fig. 29, and 187--defined as apertures--). Also, because the holes may have a non-perpendicular orientation, they may provide a positioning of the screws so

that they converge (see Fig. 3 *shown above*). The head portion also has at least three holes (Fig. 29). Also in the head portion, because it curves upward, it may be considered in a different plane than that of the shaft portion. Also, as shown in the profile of Fig. 30, a section of the head portion is thinner than the shaft. The device of Chapman et al. has holes that are capable of provisional fixation, where any of those holes may be used for a suture.

Chapman et al., however, does not disclose holes that are at least partially threaded or that have thinner cross sections in the regions of the plate between the holes, hole angles that range from 0 to 15 degrees, a multiple lead thread, or a plate that curves along a direction transverse to the longitudinal axis of the shaft portion. Bono discloses the items directly *supra* including threads (123) or multiple-lead threads(124) that enable the bone screws to be frictionally and securely locked into the plate to prevent movement when attached to the bone (Col. 2, lines 42-45), a plate cross section that shows a thinner cross section between the holes and the plate (see Fig. 6 *above*) and a curved bottom of the plate along the shaft (see Fig. 6 *above*). These modifications allow for the plate to optimally fit in its applicable uses, such as its use in long bone fracture fixation. The thinner cross section allows the plate to bend more easily to fit into these configurations (Col. 3, liens 50-63). Also, with regards to the angled orientation, Bono teaches a range of about 5-20 degrees, which is capable of performing the functions of the claimed angulations of the holes (Col. 4, lines 60-67). Having the angles for the holes allows for the plate to be maneuvered and oriented to optimally fit into the desired application of the plate during surgery (Col. 3, lines 50-63). It would have been obvious

to one having ordinary skill in the art at the time the invention was made to construct the device of Chapman et al. having at least partially threaded screws, thinner cross sections in the plate between the holes, hole angles ranging from 0-15 degrees, a multiple lead thread, or a plate that curves along a direction transverse to the longitudinal axis of the shaft portion in view of Bono to better secure the plate to long bone during surgical fixation.

Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. '544 as modified by Bono '722 as applied to claim 73 above, and further in view of Kyle et al. '872 The combination of Chapman et al. and Bono teaches the claimed invention except for a bone plating system having at least 5 holes in the shaft portion. Kyle et al. disclose a bone plating system have at least 5 holes, allowing the plate to be better secured to the femur (Col. 4,lines 45-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Chapman as modified by Bono having at least 5 holes in the shaft portion in view of Kyle et al. to better secure the plating system to the femoral region in its intended use.

Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. '544 in view of Bono '722 as applied to claim 73 above, and further in view of Trebing. et al. (U.S. Patent No. 5,601,553). The combination of Chapman et al. and Bono disclose the claimed invention except for a plating system wherein at least two of the holes in the head portion are of different diameters. Trebing et al. disclose a device having two holes of different diameters in the head portion (see Fig. 1 *above* for

a diagram of what is considered the head and shaft) that enables the user to better secure the plate in place (Col. 1, lines 55-61). It should be noted that even though Trebing et al. discloses that the larger holes may be used for temporary screws, this reference as modified by Chapman et al. in view of Bono where all screws may be threaded in the head, enables the device of Trebing et al. to better secure the plate onto the femur. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Chapman et al. as modified by Bono. having at least two holes in the head portion of different diameters in view of Trebing et al. in order to better secure the plate to femur in use.

Claims 81-82, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. as modified by Bono as applied to claim 73 and 79 above, respectively, and further in view of Talos et al '686. The combination of Chapman et al. and Bono disclose the claimed invention except for a device having holes in the shaft portion having at least a portion that is smooth, where the smooth portion is at the upper part of the hole, and wherein the smooth upper portion tapers inward in the direction from the upper surface. Talos et al. teaches a bone plate with holes partially smooth (3), and a smooth upper portion that tapers inward (5). These modifications of the bone plate allow for the best-fitting and secure attachment of screws once attached and affiliated with the plate (Col. 1, lines 22-32, and 47-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Chapman et al. as modified by Bono having at

least holes partially smooth with an inwardly tapering upper portion in further view of Talos et al. to better secure the screws to the plate.

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. as modified by Bono as applied to claim 73 above, and further in view of Berger et al. '222. The combination of Chapman et al. and Bono disclose the claimed invention except for a shaft portion with a trapezoidal-shaped cross section. Berger et al. disclose a trapezoidal cross section capable of also being fitted in between the regions between the plate holes (see Fig. IA) for the purpose of reducing bone coverage by the shaft and promoting bone growth (Col. 2, lines 32-37).

With regard to claim 97, it would have been further obvious to one having ordinary skill in the art at the time the invention was made to construct the device the combination of Chapman et al. and Bono in view of Talos et al. having screw holes between the diameter of 5-7mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Allowable Subject Matter

Claims 60-61 and 88-89 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-

5557. The examiner can normally be reached on Monday through Friday, 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

1/23/2006

JLS

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER